

§ 880.6080

21 CFR Ch. I (4–1–12 Edition)

§ 880.6080 Cardiopulmonary resuscitation board.

(a) *Identification.* A cardiopulmonary resuscitation board is a device consisting of a rigid board which is placed under a patient to act as a support during cardiopulmonary resuscitation.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 880.9. The device is also exempt from the current good manufacturing practice requirements of the quality system regulation in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

[45 FR 69682–69737, Oct. 21, 1980, as amended at 66 FR 38805, July 25, 2001]

§ 880.6085 Hot/cold water bottle.

(a) *Identification.* A hot/cold water bottle is a device intended for medical purposes that is in the form of a container intended to be filled with hot or cold water to apply heat or cold to an area of the body.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 880.9. The device is also exempt from the current good manufacturing practice requirements of the quality system regulation in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

[45 FR 69682–69737, Oct. 21, 1980, as amended at 66 FR 38805, July 25, 2001]

§ 880.6100 Ethylene oxide gas aerator cabinet.

(a) *Identification.* An ethylene oxide gas aerator cabinet is a device that is intended for use by a health care provider and consists of a cabinet with a ventilation system designed to circulate and exchange the air in the cabinet to shorten the time required to remove residual ethylene oxide (ETO) from wrapped medical devices that have undergone ETO sterilization. The

device may include a heater to warm the circulating air.

(b) *Classification.* Class II (performance standards).

§ 880.6140 Medical chair and table.

(a) *Identification.* A medical chair or table is a device intended for medical purposes that consists of a chair or table without wheels and not electrically powered which, by reason of special shape or attachments, such as food trays or headrests, or special features such as a built-in raising and lowering mechanism or removable arms, is intended for use of blood donors, geriatric patients, or patients undergoing treatment or examination.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 880.9. The device is also exempt from the current good manufacturing practice requirements of the quality system regulation in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

[45 FR 69682–69737, Oct. 21, 1980, as amended at 66 FR 38805, July 25, 2001]

§ 880.6150 Ultrasonic cleaner for medical instruments.

(a) *Identification.* An ultrasonic cleaner for medical instruments is a device intended for cleaning medical instruments by the emission of high frequency soundwaves.

(b) *Classification.* Class I. The device, including any solutions intended for use with the device for cleaning and sanitizing the instruments, is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 880.9.

[45 FR 69682–69737, Oct. 21, 1980, as amended at 54 FR 25050, June 12, 1989; 59 FR 63011, Dec. 7, 1994; 66 FR 38805, July 25, 2001]

§ 880.6175 [Reserved]

§ 880.6185 Cast cover.

(a) *Identification.* A cast cover is a device intended for medical purposes that is made of waterproof material and

placed over a cast to protect it from getting wet during a shower or a bath.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 880.9. If the device is not labeled or otherwise represented as sterile, it is also exempt from the current good manufacturing practice requirements of the quality system regulation in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

[45 FR 69682-69737, Oct. 21, 1980, as amended at 66 FR 38806, July 25, 2001]

§ 880.6190 Mattress cover for medical purposes.

(a) *Identification*. A mattress cover for medical purposes is a device intended for medical purposes that is used to protect a mattress. It may be electrically conductive or contain a germicide.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 880.9. If the device is not labeled or otherwise represented as sterile, it is also exempt from the current good manufacturing practice requirements of the quality system regulation in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

[45 FR 69682-69737, Oct. 21, 1980, as amended at 59 FR 63011, Dec. 7, 1994; 66 FR 38806, July 25, 2001]

§ 880.6200 Ring cutter.

(a) *Identification*. A ring cutter is a device intended for medical purposes that is used to cut a ring on a patient's finger so that the ring can be removed. The device incorporates a guard to prevent injury to the patient's finger.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 880.9. The device also is exempt from the current good manufacturing practice require-

ments of the quality system regulation in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

[45 FR 69682-69737, Oct. 21, 1980, as amended at 66 FR 38806, July 25, 2001]

§ 880.6230 Tongue depressor.

(a) *Identification*. A tongue depressor is a device intended to displace the tongue to facilitate examination of the surrounding organs and tissues.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 880.9. If the device is not labeled or otherwise represented as sterile, it is also exempt from the current good manufacturing practice requirements of the quality system regulation in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

[45 FR 69682-69737, Oct. 21, 1980, as amended at 66 FR 38806, July 25, 2001]

§ 880.6250 Patient examination glove.

(a) *Identification*. A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

(b) *Classification*. Class I (general controls).

[45 FR 69682-69737, Oct. 21, 1980, as amended at 53 FR 1604, Jan. 13, 1989; 66 FR 46952, Sept. 10, 2001]

§ 880.6260 Filtering facepiece respirator for use by the general public in public health medical emergencies.

(a) *Identification*. A filtering facepiece respirator for use by the general public in public health medical emergencies is a device that is a disposable half-facepiece non-powered air-purifying particulate respirator intended for use to cover the nose and mouth of the wearer to help reduce wearer exposure to pathogenic biological airborne particulates